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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,555	07/25/2003	Martin S. Linsell	P-154-US1	3562
27038	7590	01/19/2005	EXAMINER	
THERAVANCE, INC. 901 GATEWAY BOULEVARD SOUTH SAN FRANCISCO, CA 94080			KUMAR, SHAIENDRA	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,555

Applicant(s)

LINSELL ET AL.

Examiner

SHAIENDRA - KUMAR

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 12-19 and 27-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 20-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/25/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/25/03, 8/5, 8/9, en.</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicants' communication filed on 11/17/04.

Claims 1-40 are pending in this application.

1. Applicant's election with traverse of Group I, claims 1-11 and 20-26 in the reply filed on 11/17/04 is acknowledged. The traversal is on the ground(s) that the examiner has not met the proper criteria in restricting out various groups. This is not found persuasive because for example, with respect to Group I and II, applicants allege that the examiner has failed to demonstrate that Group I and II are distinct. The examiner disagrees, because the distinctness has been established and there will be undue burden on the PTO to examine additional therapeutic agents. With respect to Group I and III, applicants argue that they are claiming polar solvents. Inasmuch as there are divers polar solvents, each is distinct and hence restriction is proper. With respect to Group I and V, applicants are merely stating a probability that the examiner's suggestion may not necessarily result into pharmaceutical composition. Applicants have not provided any substantial evidence and examiner maintains his position. With respect to Group I and VI, page 3 of the instant specification does mention treatment of various diseases on lines 14-20. With respect to Group I and IV, the examiner has correctly pointed out that the invention of Group I can be administered in a metered dose.

Thus claims 12-19 and 27-40 are withdrawn from the consideration being drawn to the non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 7/25/03, 8/5/04, 8/9/04 and 11/17/04, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-11 and 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moran et al(US 6,576,793).

Moran et al teach structurally similar compounds, and composition as claimed herein. See for example, Fig 15, compound 72. The difference between the reference and herein claimed compounds is that the reference is not teaching stereoisomeric form of the compound and the physical characteristic of the compound with respect to X-ray diffraction pattern.


It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain optically active isomeric form of the Moran et al compound, because the reference compound is the same compound as claimed herein and it is obvious that the reference compound does contains mixture of isomeric forms and an optically active isomer is unpatentable over a prior art racemate, absent evidence to the contrary. With regards to the physical characteristics, they are inherent to the compounds. In re Adamson et al, 125 USPQ 233; Brenner et al v. Ladd. Comr. Pats 147 USPQ 87.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAIENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
1/14/05